STATE OF MICHIGAN

COURT OF APPEALS

BARBARA J. MICHAL, as Personal Representative of the Estate of KRISTOPHER MICHAL,

Plaintiff-Appellant/Cross-Appellee,

v

PDK LABS, BDI PHARMACEUTICALS, HAMMER CORPORATION, and 7ELEVEN INC.,

Defendants-Appellees/Cross-Appellants.

UNPUBLISHED
September 18, 2003

No. 234943
Saginaw Circuit Court
LC No. 00-0032585-NP

Before: Whitbeck, C.J., and White and Donofrio, JJ.

WHITE, J. (*concurring in part and dissenting in part*).

I respectfully dissent as to the manufacturers.[1] The circuit court's scheduling order set a discovery cut-off date of May 25, 2001. In early February 2001, just days after expert witness lists were filed in accordance with the scheduling order, Hammer filed its dispositive motion.[2]

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[1] I agree with the affirmance of the grant of summary disposition to 7Eleven. MCL 600.2947(6).

[2] Plaintiff filed her complaint on March 13, 2000. Defendants filed answers around May 2000. The circuit court entered an amended scheduling order in September 2000, stating that discovery would close on May 25, 2001. The parties filed fact witness lists in late November 2000. Defendants filed expert witness lists on January 24, 30 and 31, 2001, and plaintiff filed her expert witness list on January 29, 2001. Ten days later, on February 8, 2001, defendant Hammer filed its motion for summary disposition, noticing it for hearing on March 5, 2001. Plaintiff filed her response to defendant's motion on February 26, 2001, and, along with many other arguments, contended that because discovery remained open, a grant of summary disposition would be premature. PDK and BDI moved for summary disposition in March 2001. The circuit court heard the motions on April 2, 2001, at which time the court permitted plaintiff to submit supplemental documentary evidence, and she did so on April 4, 2001. Included were plaintiff's supplementary answers to interrogatories of defendant Hammer regarding plaintiff's experts' opinions and the experts' curriculum vitaes.

PDK and BDI filed their dispositive motion on March 12, 2001. Plaintiff's briefs opposing defendants' motions raised, inter alia, that discovery remained open and that experts had not yet been deposed.

The circuit court heard defendants' dispositive motions on April 2, 2001, more than seven weeks before the discovery cut-off date of May 25, 2001. Its opinion largely concluded that plaintiff had failed to come forward with documentary evidence sufficient to avoid summary disposition. The rush to judgment in this case occurred at the expense of developing a record sufficient to allow an informed and comprehensive review of the claims.[3] In a case of this complexity, prudence dictates that there be sufficient time to develop a complete exposition of the experts' opinions.

The documentary evidence plaintiff submitted below included a letter from the FDA's Division of Labeling and Nonprescription Drug Compliance to defendant Hammer's President, date-stamped June 10, 1997, less than two months after plaintiff's decedent's death. The letter informed Hammer that Maximum Strength Efedrin did not qualify as a bronchodilator and expectorant under the applicable federal regulations, and was considered a "new drug," which may not be legally marketed without an approved New Drug Application. The letter also stated that the drug was misbranded because the directions for use were inadequate for its intended purpose. The letter continued that the stated violations were not meant to be an all-inclusive list of deficiencies and requested immediate action to correct the violations.

The FDA's letter to defendant Hammer stated that Maximum Strength Efedrin must go through a new product application process, and that the product had labeling deficiencies. The FDA letter thus supports plaintiff's argument below that Hammer's product had not been "approved for safety and efficacy" by the FDA as required for MCL 600.2946(5) to apply. Labeling deficiencies would also render MCL 600.2964(5)'s protection inapplicable.

Plaintiff also asserted that the FDA sent defendant BDI a letter[4] informing it of violations. The letter stated that the trade name "Mini Thin" suggests that the product is intended to aid in weight loss, an unapproved use. The letter informed BDI that the FDA considered the drug to be a new drug, which may not be legally marketed because not the subject of an approved New Drug Application.

The circuit court permitted plaintiff to submit additional documentation after the April 2, 2001 dispositive motion hearing. Plaintiff submitted responses to interrogatories dated April 3, 2001 that summarized the anticipated testimony of her experts, including:

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[3] Defendant Hammer's counsel stated at the motion hearing that if the circuit court declined to grant summary disposition, plaintiff should be required to post a bond. That would have been the preferred course.

[4] Although plaintiff submitted a transcribed (and thus, unsigned) version of this letter below, BDI did not deny receiving a warning letter from the FDA, and in fact argued that if plaintiff presented such a letter, the letter was inapplicable to plaintiff's claim because it concerned use of ephedrine for weight loss purposes.

> Dr. Cunitz is expected to testify as to labeling and warning standards and/or regulations and the various ways in which the labeling on the subject products is inadequate and inconsistent with known industry standards.
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> * * *
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> It is anticipated that Dr. Gruber will testify as to the known addictive quality of ephedrine products such as those involved in the instant case and will testify as to the general knowledge available in the industry relative to these propensities.
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> . . . . It is also anticipated that Dr. Smith will be called upon to discuss the toxicology aspects of ephedrine products relative to the dangers associated with continued use in terms of elevation of blood pressure or other cardiovascular effects . . . . as well as an alternate pharmacological means of achieving the same therapeutic results without the risk(s) associated with ephedrine; he will also offer testimony relative to the cumulative effects of ephedrine when combined with caffeine or other similar stimulants and will discuss the risks associated with those combinations and will relate that to the fatal consequences occurring in this case.
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> * * *
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> It is anticipated that Dr. Smith will testify as to the unreasonable risk of addiction and other physiological problems associated with consumption of ephedrine products such as those involved in the case. It is anticipated that he will discuss alternate substances that would be equally effective as ephedrine, but pose less or no risk of cardiovascular complications.

In addition to Dr. Smith's anticipated testimony that there were alternate pharmacological means of achieving the same therapeutic results as ephedrine did, without the associated risks of ephedrine, quoted *supra*, plaintiff submitted an article stating that ephedrine is not considered as efficacious in treating asthma as it was in the past, and that newer drugs have replaced it.

For these reasons, I conclude that the grant of summary disposition to the manufacturers was premature. Plaintiff may indeed have been able to establish that there were questions of fact regarding whether defendants Hammer and PDK/BDI complied with FDA standards such that the protections of MCL 600.2946(4) and (5) would not apply; whether a practical and technically feasible alternative production practice was available that would have prevented the harm, see MCL 600.2946(2); whether it was or should have been obvious to plaintiff's decedent that misuse of the products could result in death, see MCL 600.2948(2); and whether the warnings were adequate.

/s/ Helene N. White